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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/945,425	10/21/1997	CHRISTER CEDERBERG	1103326-282	2696

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EXAMINER	
DESAI, RITA J	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 06/30/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/945,425	Applicant(s) CEDERBERG ET AL.	
	Examiner RITA J. DESAI	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,18,26 and 27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,18,26 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☑ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 31-5.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

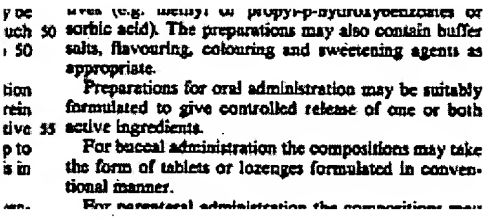
DETAILED ACTION

Claims pending 1, 2, 18, 26 and 27.

Applicants have cancelled the formulation claims and deleted the non-elected subject matter, limiting it to the elected group. However it has still not been limited to benzimidazole.

The applicants claims still contain the term comprising, which in the interview summary was agreed to be changed to consisting.

The rejection of claims 1, 2, 18, 26 and 27 under 35 USC 103 over US 5330982 Tyers still stands. Applicants arguments are not persuasive. The reference clearly teaches 1-4 times a day and the dosage range is also the same. The reference also teaches suitable formulations to give controlled release of one or both the active ingredients . See lines 53-55 in column 10 of the reference.



y be ... (e.g. methyl or propyl-p-hydroxybenzoates or
uch 50 sorbic acid). The preparations may also contain buffer
50 salts, flavouring, colouring and sweetening agents as appropriate.
tion Preparations for oral administration may be suitably
rein formulated to give controlled release of one or both
tive 55 active ingredients.
p to For buccal administration the compositions may take
is in the form of tablets or lozenges formulated in conventional manner.
... For parenteral administration the compositions may

Time release drugs work on the same principle and it would be prima facie obvious to administer smaller dosages at shorter intervals.

Thus the rejection still stands.

The rejection of claims 1,2,18,26 and 27 under 35 USC 102 over Martindale still stands .

Applicants arguments that an increase is no the same as extending a dose is not persuasive, since applicants comparison of the 20mg twice daily Vs the 40 mg once daily in the figure 1 clearly indicates a slight *increase* in the % inhibition and not an *extention* of the inhibition.

The rejection still stands.

The rejection of claims 1, 2, 18, 26 and 27 under 35 USC 103 over WO 96/01624 and Tyers 5330982 still stands.

Applicants arguments that Mardindale teaches a single dose and a higher dose may be related to only Zollinger –Ellison syndrome is not found to be persuasive , since the Tyers reference also teaches the controlled release and also that it can be administered 1-4 times daily . Applicant is not correct in indicating that the dosages given in the reference is only with respect to the 5 HT-receptor antagonist and not with respect to the H+K+ATPase inhibitors. See column 8 , 9 and 10.

The H+K+ATPase inhibitors dosages are given clearly in column 8.

Column 9 clearly states these are in two separate preparation or combinations.

Column 10 clearly also indicates the controlled release of on or both the ingredients.

and physiologically acceptable salts and solvates thereof.

Suitable H+K+ATPase inhibitors for use according to the present invention include tetrahydrothiophenes (e.g. pyridyl-2-tetrahydrothiophenes), imidazopyridines, benzoxazoles, benzthiazoles and, more particularly, benzimidazole derivatives. Examples of suitable benzimidazole derivatives include 2-(arylmethylsulphinyl) benzimidazoles (e.g. 2-[(amino-substituted phenyl)-methylsulphinyl]benzimidazoles), 2-(pyridylmethylthio) benzimidazoles, 2-(heterocyclicmethylsulphinyl)benzimidazoles and, more particularly, 2-(pyridylmethylsulphinyl)benzimidazoles. Such compounds are disclosed in for example UK Patent Specifications Nos. 1525958 and 2161160, and in European Patent Specifications Nos. 5129, 150586, 220053 and 221041. Particular examples of benzimidazole derivatives which are H+K+ATPase inhibitors are omeprazole, timoprazole, picoprazole and disuprazole.

The dose at which the 5-HT$_3$ receptor antagonist and H+K+ATPase inhibitor may be administered to man will depend upon the route of administration, the body weight of the patient, the condition being treated and its severity, and the potency of the compounds.

The H+K+ATPase inhibitor may conveniently be administered at doses within the normal dosage range at which the compound is therapeutically effective. Thus, dependent on the influencing factors referred to above, the H+K+ATPase inhibitor may be administered at doses up to, for example, 100 to 500 mg per day. A composition for use according to the invention may contain for example 5–250 mg of the H+K+ATPase inhibitor per dosage unit. Lower unit doses such as 5–100 mg or 5–60 mg (e.g. 10–60 mg) may, however, be appropriate for more potent H+K+ATPase inhibitors.

Thus a composition for use according to the invention containing a compound of formula (I) as herein defined may contain from 0.2 to 250 mg of the active ingredient per unit dose, and may be administered for example up to four times per day, such that the overall daily dose is in the range 0.5 to 500 mg.

A composition for use according to the invention containing a compound of formula (II) as herein defined may contain from about 0.5 to 100 mg of the active ingredient per unit dose, usually 1 to 50 mg and preferably 3 to 30 mg, and may be adminstered, for example, from 1 to 4 times per day.

The reference teaches that the H+K+ATPase drug can be administered separately .

In column 11 the two separate compositions are also indicated lines 39-40.

Thus there is a clear teaching that H+K+ATPase inhibitors can be administered at 1-4 times daily within the same dosage as given by the applicants.

The rejection still stands.

The rejection of claims 1, 2, 18, 26 and 27 under 35 USC 112 still stands.

The claims do not clearly indicate the .5-4 hrs interval.

Conclusion

The claims 1, 2, 18, 26 and 27 stand rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR.1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RITA J. DESAI whose telephone number is 703-305-1868. The examiner can normally be reached on Monday - Friday,9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

R.D.
June 26, 2003